

The effect of 0.24% hyaluronic acid gel used after diode laser-assisted labial frenectomy on postoperative pain level and periodontal parameters: a randomized clinical research

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ABSTRACT

Aims: Diode lasers are popular dental soft tissue lasers due to their bleeding-free and sutureless surgery advantages. Although diode lasers offer benefits in surgery, their application in frenectomy procedures for pediatric patients remains limited. Hyaluronic acid gel (HA) is a commonly used natural biopolymer for treating symptoms of wound healing. No studies have examined the effect of 0.24% HA gel on postoperative pain and periodontal outcomes after laser-assisted frenectomy in children. This research aimed to evaluate the effect of 0.24% HA gel on the healing trajectory and postoperative pain management in pediatric patients undergoing diode laser-assisted labial frenectomy.

Methods: Two groups were formed for the study: a control group consisting of 20 participants aged 8 to 14 who underwent diode laser-assisted frenectomy with sterile saline and an experimental group of 20 participants, also aged 8 to 14, who received diode laser-assisted frenectomy supplemented with HA gel. A frenectomy was performed using diode laser assistance. After the surgery, the pain level was evaluated using the visual analog scale for one week. Plaque index, gingival index, pocket depth, bleeding on probing, keratinized gingival width, and attached gingival thickness values were observed and evaluated for three months.

Results: No difference in pain levels between HA gel and the control group after one week on days 1 and 2; the group that used HA gel reported lower pain levels ($p>0.05$). The control group reported lower pain levels during the third and fourth days ($p>0.05$). During days 5-7, the group treated with HA gel reported lower pain levels ($p>0.05$). Between days 5 and 7, the HA gel participants experienced decreased pain levels. The test group also showed no significant changes in all periodontal parameters.

Conclusion: Applying 0.24% HA gel post-laser-assisted frenectomy reduced pain, although this effect did not reach statistical significance compared to the control group. Future studies should involve larger sample sizes and extended follow-up periods to investigate further HA gel's effects, particularly formulations with higher concentrations.

Keywords: Frenectomy, hyaluronic acid, diode laser, labial frenulum, Visual Analog Scale

INTRODUCTION

The labial frenulum refers to a fold of mucous membrane that consists of connective tissue and muscle fibers.¹ This mucosal membrane connects the upper lip to the gums and underlying bone through the periosteum. Frenectomy refers to the surgical procedure of removing the frenulum.²

If the labial frenulum prevents breastfeeding movements in newborns and babies, they should be surgically removed. It should be removed if it restricts lip movements, disrupts nourishment, and complicates oral hygiene maintenance in childhood.³

Indications for frenectomy include several functional and aesthetic considerations. Insufficient labial mobility can

hinder effective utensil use, particularly forks and spoons. The presence of a prominent labial frenulum may disrupt the articulation of bilabial consonants—specifically /b/, /f/, /m/, /p/, and /w/. Additionally, the normal frenulum structure plays a role in preventing mouth breathing by restricting the closure of the upper and lower lips. From an oral hygiene perspective, a restrictive frenulum can obstruct access to the vestibular sulcus, particularly in the incisors, thereby increasing the risk of caries due to compromised cleaning. Clinical indications for frenectomy also include the presence of a midline diastema greater than 2 mm, gingival recession, and aesthetic concerns such as diminished lip fullness and altered smile lines in adults. Furthermore, instability of prosthetic restorations in

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adults can necessitate surgical intervention to enhance both function and appearance.^{3,5-7}

The use of the traditional scalpel for surgical procedures has become widely accepted. The classic scalpel method has been used for years to perform labial frenectomies.¹ Surgeries using scalpels often lead to patient complaints due to bleeding, use of local anesthetic, and suturing.⁸

The reliability of lasers for dental procedures, marketed as an alternative to scalpel surgery, has been confirmed by numerous studies.² Studies show that lasers like Nd: YAG, CO₂, Er: YAG, Er, and Cr: YSGG are used for surgical procedures like gingivectomy, gingivoplasty, harvesting free gingival graft, operculectomy, and frenectomy.⁹ Diode lasers are specifically designed for soft tissue surgery and have proven effective.¹⁰ Operating on soft tissue, diode laser offers coagulation, evaporation, cutting, and sterilization features for ease of use by both operator and patient.^{5,11}

Diode lasers offer key benefits in frenectomy procedures by reducing the risk of damage to surrounding tissue and minimizing bleeding. They also lower scar tissue formation and postoperative pain, improving patient comfort. With a pre-programmed wavelength and pulse power, diode lasers ensure precise targeting of tissue while protecting adjacent structures from injury.^{9,12} Diode lasers in sutureless surgery can reduce plaque accumulation, minimize stress, and speed up recovery.¹³ Protecting against secondary trauma from speech and chewing, rapid recovery can significantly enhance patient comfort.¹⁴

Numerous wound care products have been developed to maintain cleanliness in the wound area and speed up healing.¹⁵ This helps enhance patient comfort by promoting faster recovery during the postoperative period and enables the patient to return to their preoperative routine sooner.¹⁶ Chlorhexidine is the most well-known.¹⁴ While sodium hypochlorite, hydrogen peroxide, and povidone-iodine are commonly used, they are cytotoxic to epithelial cells.^{14,17} Although there is still controversy surrounding the use of topical drugs in pediatrics, the primary concern is the ability to swallow the drugs.¹⁸ Swallowable wound care products made with natural ingredients have gained popularity due to safety concerns.^{15,19} Hyaluronic acid (HA), which has gained popularity in dentistry recently, was first discovered and isolated in the vitreous humor of the eye in 1934 and named "Hyaluronan." HA is the most fundamental glycosaminoglycan form.¹⁶ HA is a naturally occurring biopolymer with biocompatibility and moisture-retaining properties.²⁰ In dentistry, it effectively manages gingivitis and periodontitis, aids in papillary reconstruction, and promotes wound healing in periodontal tissues, enhancing tissue regeneration.²¹⁻²³ It is also helpful in accelerating bone healing in the socket after tooth extraction, aiding in regenerating the temporomandibular joint, treating oral aphthous ulcers, and providing symptomatic relief as a teething gel for infants and young children.¹⁶ Although there is a recommendation to use HA gel for these pathologies, there are only a limited number of studies evaluating its use after frenectomy. Only one research has assessed the use of HA gel in frenectomies carried out with a diode laser.¹⁴

In this research, the null hypothesis is that using 0.24% HA during frenectomies performed with diode laser will decrease postoperative pain levels in patients and improve periodontal parameters compared to the group not receiving HA treatment.

METHODS

The study was conducted with the approval of Afyonkarahisar University of Health Sciences Clinical Researches Ethics Committee (Date: 14.06.2019, Decision No: 2019/7) between April 2019 and August 2020. The research conducted follows the ethical principles outlined in the Declaration of Helsinki. We used G-Power version 3.1 (Informer Tech Inc. Germany) to determine the number of research participants. We considered an effect size of 0.5.²⁴ It was determined that each group should have 16 individuals for 95% power at a 5% significance level. Despite this, the research included total 40 pediatric patients during the selected dates. However, 12 out of the 40 patients were excluded at the end of the research. Eventually, the control and experimental groups consisted of 14 patients each.

Inclusion Criteria

Children who have not received any antibiotic treatment in the past four months. Children who do not have any underlying systemic diseases. Children who are not required to take medication regularly. Both girls and boys between the ages of 8 and 14. Children and their parents willing to participate in the study and attend the control session one week later were included.

Exclusion Criteria

The patient presents with periodontal disease. Children with cognitive disabilities, including autism and attention deficit hyperactivity disorder, as well as those with mental health conditions such as cerebral palsy and Down syndrome. Children and their parents who do not meet the specified criteria were excluded from the study.

Frenectomy was indicated, and informed consent forms were obtained from willing parents. At the end of the research, only 28 patients could participate fully. This was due to some patients not accurately completing the Visual Analog Scale (VAS) (Figure 1), being unable to apply the HA Gel as instructed, and failing to attend their follow-up appointments.

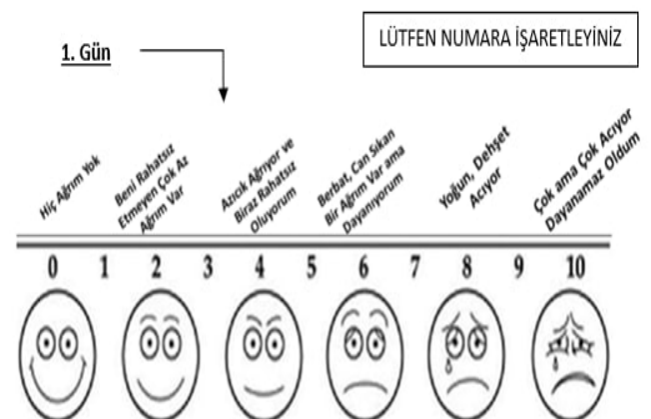


Figure 1. Visual analog scale

According to the behavioral guidance protocol, the researcher ÖD informed the patients about the procedures and assisted them in getting comfortable in the dental chair.²⁵ In the research, various periodontal parameters such as plaque index²⁶ (PI), gingival index²⁶ (GI), pocket depth (PD), bleeding on probing (BOP), keratinized gingival width¹¹ (KGW), and attached gingival thickness¹¹ (AGT) were measured for all patients. These measurements were performed using a periodontal probe (HuF No:15, Hu Friedy, Chicago, IL, USA) on both the maxillary right incisor (11) and the maxillary left incisor (21).^{11,14} PI, GI, and PD values were measured from 6 different points of teeth 11-21: mesiobuccal, buccal, distobuccal, distopalatal, palatal, and mesiopalatal. The obtained values were averaged to create a single value.^{11,14} Another researcher who performed periodontal measurements who did not complete the frenectomy, conducted the frenectomy.^{3,4,13,27}

Before topical anesthesia, pediatric patients' frenectomy areas were wiped with a dry cotton pellet and dried. Topical anesthesia was achieved using locanest spray, which contains 10% lidocaine (Avixa İlaç San. in Başakşehir, İstanbul, Turkey). The topical anesthesia solution was applied to cotton pads and left on the right and left areas of the frenulum attachment for 1 minute to provide topical anesthesia. The frenulum area was injected with 2% articaine solution containing 1:100,000 adrenaline, 0.5 ml to the right and left for local anesthesia.¹⁴

The usage protocol for the diode laser was initiated after a wait of around 10 minutes. In this research, the diode laser used was the BIOLASE Epic10™ (BIOLASE INC., CA, USA). The laser interface has been set to "Frenectomy" mode. The features of the frenectomy mode are shown in **Table 1**.

Table 1. Parameters of BIOLASE epic 10™ diode soft tissue laser

BIOLASE epic 10™ diode soft tissue laser	
Wavelength	940±10
Maximum power of the equipment	10 Watts (W)
Operating mode	Puls mode
Used power	1.0 W
Irradiation mode	The activation occurs once the pedal is pressed and the targeted tissue is contacted.
Used optic fiber tip diameter	400 micrometer/7 mm
Pulse duration	1 millisecond
Pulse interval	1 millisecond
Peak power	2.0 W
Average	1.0 W

After the patient and the operator wore protective glasses, environmental safety measures were taken before the frenectomy procedure, following the guidelines in **Table 1**.

Using brushing movements, the laser was applied to the frenulum's upper and lower parts near the hemostat. It also removed the remaining muscular attachments of the periosteum to eliminate the periosteal adhesion. The remaining ablated tissue was cleared using a moistened gauze with a sterile saline solution.^{10,11} The average time taken for the procedure was 120 seconds with the diode laser (**Figure 2**). Post-surgical instructions for participants included guidelines for the application of HA gel. Individuals in the 0.24% HA cohort received seven disposable blister packs, each containing aftamed child gel (0.24% HA, Aktident, Üsküdar,

Istanbul, Turkey). Patients were directed to apply the HA gel to the wound site three times daily for one minute following the instructions for use, starting each application with a fresh blister pack.²⁸ They were also advised to abstain from ingestion of food or liquids for 10 to 15 minutes following each application to optimize the gel's efficacy.¹⁴

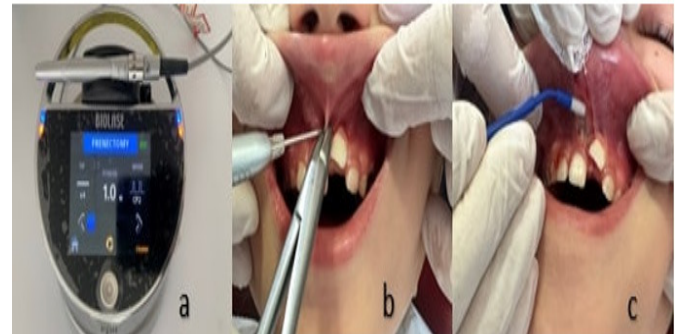


Figure 2. The stages of a frenectomy procedure that utilizes the diode laser. **a.** The epic 10 diode laser. **b.** Surgical procedure of the diode laser assisted-frenectomy. **c.** The application of 0.6% HA gel for demonstration for parents HA: Hyaluronic acid

Parents of patients who had frenectomy were instructed on completing the VAS.²⁹ A visual VAS was given to patients to rate their pain level each evening, including the night of the frenectomy. According to this scale, 0 means I have no pain, and 10 means I have unbearably great pain. (**Figure 1**) From the evening of the transaction day, the VAS was completed for seven consecutive evenings, with a numerical value assigned to each entry.^{5,10} It was decided not to measure the periodontal parameters again after the first week to avoid discomfort for the children with inflamed wound areas. During the 1st week of control after the frenectomy, the patients were given oral hygiene training again and were called back for control at the end of the 3rd month. Patients with scheduled 3rd-month follow-up appointments were reminded by phone and encouraged to attend. At the end of the third month, another operator repeated the PI, GI, PD, BOP, KGW, and AGT values without verifying whether the patient belonged to the control or test groups. The patients and their parents were reminded about oral hygiene training and informed that the research had been completed (**Figure 3**).

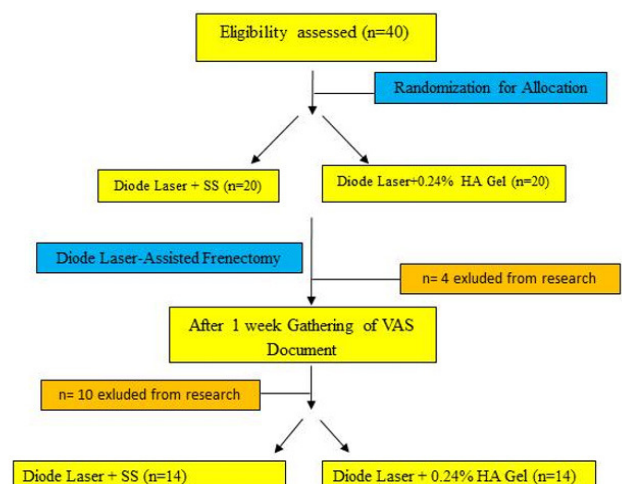


Figure 3. Flow diagram of the research

Statistical Analysis

The data analysis was conducted using the SPSS version 21 program. Descriptive statistics such as standard deviation and median (minimum-maximum) were utilized to analyze quantitative variables. The Fisher exact test examines the relationship between two qualitative variables the Repeated Measures ANOVA test was used to compare measurements within groups. A significance level of 0.05 was set for statistical analysis.

RESULTS

In the diode laser+SS group, there was a significant difference in VAS measurements taken at seven different time points ($p<0.001$). The mean VAS score was highest on day one and lowest on day seven. It is observed that the significant difference between the first and fourth day is the highest among all pairs of days ($p=0.017$), first-sixth day ($p=0.007$), first-seventh day ($p=0.007$), second-six day ($p=0.043$), and second-seventh day ($p=0.043$) (Figure 4).

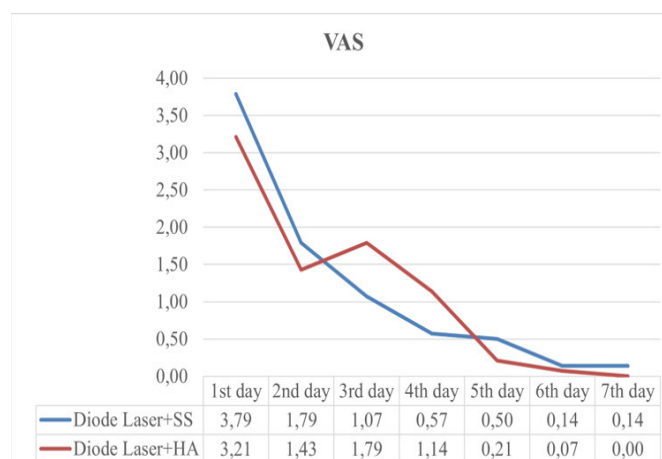


Figure 4. The time-dependent changes in VAS for the diode laser+SS and diode laser+HA groups
VAS: Visual analog scale, HA: Hyaluronic acid

There was a significant difference in the VAS measurements taken seven times in the group that received diode laser+HA. diode laser+HA ($p<0.001$). The mean VAS score was highest on the first day and lowest on the seventh. It is observed that the significant difference between the seven days occurs between the first and fifth days ($p=0.034$), first-sixth day ($p=0.012$), first-seventh day ($p=0.010$), second-fifth day ($p=0.029$), second-sixth day ($p=0.009$), and second-seventh day ($p=0.016$) (Figure 4).

Table 1 shows no significant difference in variables between the two groups ($p>0.05$). Three monthly changes showed no difference in the diode laser+SS group. An increase in PI value was observed in 21.4% of patients in the diode laser+HA group, while a decrease was observed in 7.1%. ($p=0.098$) When compared monthly, there was a 7.1% decrease in the PI value of tooth number 21 for patients in the diode laser+SS group. In the diode laser+HA group, 14.3% of the patients experienced a decrease in PI value, while 7.1% experienced an increase ($p=0.596$).

During the first three months, 7.1% of diode laser+SS group patients showed a decrease in GI value for tooth number 11. 7.1% of patients in the diode laser+SS group showed a

decrease in GI value from the beginning to 3 months in tooth 11. ($p=0.730$). 7.1% of patients in the diode laser+SS group showed a decrease in GI value in tooth 21 during the first three months. In the diode laser+HA group, 14.3% of patients experienced a decrease in GI value, while 7.1% experienced an increase. ($p=0.596$) (Table 2).

Table 2. Comparisons of baseline-3 month changes in variables between two groups

Variables	Diode laser+SS	Diode laser+HA	p
PI 11	No change 14 (100.0)	10 (71.5)	0.098 ^a
	Decrease 0 (0.0)	1 (7.1)	
	Increase 0 (0.0)	3 (21.4)	
PI 21	No change 13 (92.9)	11 (78.6)	0.596 ^a
	Decrease 1 (7.1)	2 (14.3)	
	Increase 0 (0.0)	1 (7.1)	
GI 11	No change 13 (92.9)	11 (78.6)	0.730 ^a
	Decrease 1 (7.1)	1 (7.1)	
	Increase 0 (0.0)	2 (14.3)	
GI 21	No change 13 (92.9)	11 (78.6)	0.596 ^a
	Decrease 1 (7.1)	2 (14.3)	
	Increase 0 (0.0)	1 (7.1)	
PD 11	No change 12 (85.7)	11 (78.6)	0.108 ^a
	Decrease 2 (14.3)	0 (0.0)	
	Increase 0 (0.0)	3 (21.4)	
PD 21	No change 12 (85.8)	11 (78.6)	1.000 ^a
	Decrease 1 (7.1)	1 (7.1)	
	Increase 1 (7.1)	2 (14.3)	
BOP 11	No change 12 (92.3)	9 (75.0)	0.390 ^a
	Decrease 1 (7.7)	2 (16.7)	
	Increase 0 (0.0)	1 (8.3)	
BOP 21	No change 12 (92.3)	11 (91.7)	1.000 ^a
	Decrease 1 (7.7)	1 (8.3)	
	Increase -	-	
KGW 11	No change 11 (78.6)	10 (71.4)	0.648 ^a
	Decrease 1 (7.1)	0 (0.0)	
	Increase 2 (14.3)	4 (28.6)	
KGW 21	No change 13 (92.9)	12 (85.7)	1.000 ^a
	Decrease -	-	
	Increase 1 (7.1)	2 (14.3)	
AGT 11	No change 13 (92.9)	12 (100.0)	1.000 ^a
	Decrease -	-	
	Increase 1 (7.1)	0 (0.0)	
AGT 21	No change 13 (92.9)	12 (100.0)	1.000 ^a
	Decrease -	-	
	Increase 1 (7.1)	0 (0.0)	

HA: Hyaluronic acid, a: Fisher-exact test

Only 14.3% of patients in the diode laser+SS group showed decreased PD value when comparing tooth 11 from baseline to 3 months. An increase in pocket depth was only observed in 21.4% of patients in the diode laser+HA group. ($p=0.108$). After examining the PD change in tooth 21 from baseline to 3 months, it was noticed that 7.1% of the patients in the diode laser+SS group experienced a decrease in PD value, while 7.1% saw an increase in their pocket depth value. A decrease in PD was observed in 7.1% of patients who received diode laser+HA, while an increase was observed in 14.3%. ($p=1.000$) (Table 2).

When analyzing the first 3-month change in BOP of tooth #11, 7.7% of patients in the diode laser+SS group had a decrease in BOP value. In the group that received diode laser therapy plus HA, 16.7% of patients experienced a decrease in BOP value, while 8.3% experienced an increase in BOP value ($p=0.390$). 7.7% of patients in the diode laser+SS group showed a decrease in BOP value in tooth 21 during the initial 3-month period.

An 8.3% decrease in BOP value was observed among patients in the diode laser+HA group ($p=1.000$) (**Table 2**).

The KGW change in tooth 11 from the initial to the third month showed that 7.1% of patients in the diode laser+SS group had a reduction in KGW value, while 14.3% showed an increase in KGW value. An increase in KGW value was observed in 28.6% of patients who received diode laser and HA treatment. ($p=0.648$). 7.1% of patients in the diode laser+SS group showed increased KGW value in tooth number 21 during the initial three months. An increase in the KGW value was observed in 14.3% of the patients in the diode laser+HA group ($p=1.000$) (**Table 2**).

After three months, the change in AGT values in tooth number 11 was observed in 7.1% of patients in the diode laser+SS group. No changes were observed in the AGT value of patients in the diode laser+HA group ($p=1.000$). There was an increase in AGT value for 7.1% of patients in the diode laser+SS group when comparing AGT at the initial and three months later in tooth number 21. No changes were observed in the AGT value of patients in the group treated with diode laser and HA ($p=1.000$) (**Table 2**).

DISCUSSION

It was found that using 0.24% HA gel during frenectomy diode laser-assisted surgery did not significantly reduce patient pain levels. After frenectomy, it was found that 0.24% HA did not significantly improve periodontal parameters. Based on the results, the research's null hypothesis was rejected.

The research included children aged 8 to 14 to increase treatment success. While anxiety and fear are often used interchangeably, they are distinct experiences. Dental anxiety is the fear of experiencing pain or discomfort during dental procedures. Dental anxiety is a common fear of dental procedures, including stimuli, devices, tools, and needles.³⁰ Previous studies have revealed that dental anxiety among children falls within the range of 21.3% to 23.5%.³¹ This anxiety disorder experienced in pediatric patients poses a challenge, especially in surgical procedures performed under local anesthesia. Behavioral guidance techniques are used for older children instead of sedation/general anesthesia during surgical procedures.²⁵

Children perceive and express pain differently than adults.³² Pain perception is affected by physiological, psychological, behavioral, and developmental factors, which make its expression complex.³³ It is easier to define and measure the pain level in adolescents than in newborns and young children, who often experience difficulty in expressing their pain and determining its level.³⁴ During studies on frenectomy, the degree of post-operative pain was primarily assessed using VAS.^{5,11,14,35} The pain level of pediatric patients was evaluated using VAS in this research.²⁹

Diode laser, widely used in soft tissue-related procedures, has recently gained popularity.¹⁰ Solid-state semiconductor diode lasers are composed of aluminum, gallium, and arsenide. It produces light in the near-infrared spectral region with a wavelength range of 808-980 nm.³⁶ Frenectomy surgeries can have difficult bleeding control, and sutures can impede

healing and make patients uncomfortable during recovery.³⁷ Cleaning a wound with sutures and plaque can slow post-op healing and affect speech and chewing.¹¹

High molecular weight HA gel exhibits high viscosity, elasticity, and negative energy charge. It has been widely used in dentistry for the past decade. HA gel has several beneficial properties, including bacteriostatic, fungistatic, anti-inflammatory, antiedematous, osteoinductive, and proangiogenic effects.³⁸⁻⁴⁰ It was recommended to alleviate symptoms of gingivitis, periodontitis, bone healing, oral ulcers, and teething and improve the aesthetics of the lips and jawline.⁴¹ Despite its recommendation after surgical procedures, there are still limited studies on the effectiveness of topical HA gel after frenectomy in pediatric patients.^{14,42}

In this research on labial frenectomy-assisted diode laser, periodontal parameters, including PI, GI, BOP, PD, KGW, and AGT, were measured and monitored over three months. However, no significant changes were detected in any of these parameters for either the control or test groups. Previous studies have revealed no significant differences in the periodontal parameters evaluated compared to the current results.^{5,10,11,14}

Öztürk Özener et al.¹⁰ found no significant change or recurrence in the KGW parameter after a 12-month follow-up for frenectomy operations using diode laser or conventional scalpel surgery. In related research, Sezgin et al.⁵ found no significant change in the KGW parameter over a 12-month follow-up period. In this research, an analysis of the KGW values for teeth numbers 11 and 21 revealed an increase in the KGW values within the 0.24% HA treatment group; however, this increase did not reach statistical significance. Uraz et al.¹¹ found that the AGT parameters no significant change in AGT over six months, consistent with present research. This study's application of 0.24% HA demonstrated no significant alteration in AGT levels following a diode laser frenectomy procedure.

Limitations

There are some limitations to this research. The research's most significant limitation is the number of patients enrolled. Researchers faced a considerable challenge when conducting the research with a larger participant pool. In the group of young patients, keeping them calm and relaxed during dental procedures was quite challenging, especially when using a laser. One of the reasons for this challenge is that the patients needed to be administered sedation. Another factor to consider is the behavioral disorder caused by wearing protective equipment, including glasses. Many patients refuse to regularly use HA gel and SS provided in 10cc syringes, resulting in fewer research participants. The parents of certain patients expressed this situation to the researchers. These patients were excluded from the research. Due to the COVID-19 pandemic, many participants canceled their procedures or missed follow-up appointments.

The follow-up for participants in this research after one month was conducted similarly to previous studies.^{5,10,11,14} At the end of the research, the participants' periodontal parameter values in the 1st and 3rd months were almost identical. To

simplify the statistical analysis and improve the readability of the research, only the initial and 3rd-month periodontal parameter results are presented. Studies with longer follow-ups focus on the KGW parameter in the literature; only one research by Uraz et al.¹¹ three reported recurrence in a few patients following diode laser-assisted frenectomy. However, Pie-Sanchez et al.⁴³, Sezgin et al.⁵, and Öztürk Özener et al.¹⁰ stated no recurrence in the KGW parameter after 12 months of follow-up. It is important to note that all of these studies were conducted on adult patients. If the follow-up period is shorter, it may be easier to fully understand the reasons for parameter changes as pediatric patients continue to grow and develop. This study employed a non-blinded design, wherein all control procedures were carried out by the same clinicians (SSAD and NCK). A potential limitation of this approach is the likelihood that the findings may have been influenced by the inherent characteristics of the study design.

CONCLUSION

The 0.24% HA Gel Diode was ineffective in reducing pain perception after a laser-assisted frenectomy. Furthermore, it did not contribute to improving any other periodontal parameters that were assessed. Using higher concentrations of HA gel in future studies can validate the results and determine the effective concentration after frenectomy with the diode laser.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was conducted with the approval of Afyonkarahisar Health Sciences University Clinical Researches Ethics Committee (Date: 14.06.2019, Decision No: 2019/7).

Informed Consent

Parents of all patients signed a free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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